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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/037,657	03/10/1998	TRACY WILLSON	10857Z	7400

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EXAMINER

HAMUD, FOZIA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 05/15/2003

30

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/037,657

Applicant(s)

WILLSON ET AL.

Examiner

Fozia M Hamud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 20-27, 35-40 and 42-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 43-48 is/are allowed add.
- 6) ☐ Claim(s) 20-27, 35-40, 42, 49-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### **DETAILED ACTION**

1. Receipt of Applicants' arguments and amendments filed on 21 February 2003, in Paper No.29 is acknowledged. Claims 20, 26, 35, 37, 39, and 42 have been amended, claim 41 has been canceled and new claims 49-56 have been added. Thus claims 20-27, 35-40, 42-56 are pending and are under consideration.

#### **Response to Amendment:**

##### **Specification**

2. Applicants' statement that a certified copy of the Australian Patent Application PO2246/96 was submitted to USPTO on December 1, 1997 in the parent application, 08/928,720 is accurate, therefore it is not necessary to resubmit this document.

3. The following previous objections and rejections are withdrawn in light of Applicants amendment filed in Paper No: 29, filed on 02/21/03:

(I) The rejection of claim 42 made under 35 U.S.C § 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention is withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 20-27 and 35-38 stand rejected and new claims 49-56 are rejected under 35 U.S.C.§ 112 , first paragraph for reasons of record set forth in the office action mailed on 16 May 2000 in Paper NO:12 and reiterated in the final office action mailed on 05 January 2001 pages 3-6 and again reiterated in the office action mailed on 08/13/02 in Paper NO:27.

Applicants argue that the substitution of an amino acid for a conformationally similar amino acid with similar hydrophobic or hydrophilic properties would have been routine at the time the present application was filed. Applicants further submit that based on the teachings of the present specification, it would have been routine for one skilled in the art to generate any number of polypeptides which are not 100% identical to the polypeptides of SEQ ID Nos: 12, 15, 17, 19, 25 or 29 and to determine whether these polypeptides have a desired activity.

These arguments have been fully considered, but is deemed unpersuasive for the following reasons: firstly, instant claims 20-27 and 35-38 and 49-54 do not recite specific amino acid substitutions and the specification does not teach which amino acids of the claimed polypeptides should be substituted with conformationally similar amino acids with similar hydrophobic or hydrophilic properties. Secondly, in terms of amino acid sequence homology, a single mutation in a protein is capable of altering biological activity and it is not predictable which amino acids are necessary for activity without first testing and determining those amino acids which are required for biological activity. Thirdly, Applicants do not disclose one single polypeptide that is encoded by a nucleotide sequence that is at least 85% identity to SEQ ID Nos: 12, 14, 16, 18, 24 or 28. Instant specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a nucleotide having at least 85% sequence identity to the nucleotide sequence set forth in SEQ ID NOs: 12, 14, 16, 18, 24 or 28 which encodes a functional haemopoietin receptor, nor does the disclosure provide criteria that explicitly enable such critical

Art Unit: 1647

features. Furthermore, one of ordinary skill in the art would not be able to envision the structure or predict which ones of the almost infinite number of variants that could be made, would retain the desired function. Instant specification has not provided guidance or information as to which sites should be conserved and which sites could be modified without affecting the functional property of the protein. The issue is not whether the skilled artisan can generate polypeptides having less than 100% identity to the claimed polypeptides, but which part of the polypeptides should be altered without affecting the activity of the polypeptides. Instant specification lacks proper guidance to enable the skilled artisan to make and use polypeptides which are not 100% identical to the polypeptides of SEQ ID Nos: 13, 15, 17, 19, 25, or 29 but still retain a desired property of said polypeptides without undue experimentation, because of the unpredictability of the art of amino acid substitutions, deletions or additions. Therefore, instant specification does not provide sufficient support under the first paragraph of 35 U.S.C. § 112 for claims which encompass variants comprising 90% to the polypeptides of SEQ ID Nos: 13, 15, 17, 19, 25 or 29, or those encoded by a nucleotide sequence having at least 85% identity to SEQ ID Nos: 12, 14, 16, 18, 24 or 28, which further comprise the amino acid motif set forth in SEQ ID No:1.

6. Claims 20-27 and 39-40, 42 stand rejected and new claims 49-56 are rejected under 35 U.S.C. § 112 , second for not reciting specific high stringency hybridizations conditions for reasons of record, set forth in the office action mailed on 01/05/01 in Paper NO:17, page 7 and reiterated in the office action mailed on 08/13/02 in Paper NO:27.

Art Unit: 1647

6a. Claims 20 and 49 still recite "...under high stringent condition" without properly defining these conditions. Applicants did not address this rejection, as far as it pertains to claim 20.

6b. Instant claims 39 and 54 recite a range of hybridization conditions, however, the recited hybridization conditions are neither high stringency nor low stringency. Although the low wash temperature is considered to be low stringency, the wide range of salt concentrations make these conditions unclear. High wash temperature and low salt concentrations are considered to be high stringency conditions. The stringency conditions recited in claims 42 and 56 are considered to be high stringency and have support in the specification.

Claims 21-27, 40, 42 and 50-56 are rejected as being vague and indefinite insofar as they depend on claims 20, 39 and 49 for the limitations set forth directly above.

#### Conclusion

7. Claims 43-48 and are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1647

**Advisory Information**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursday from 7:30AM to 4:00PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4556. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
05 May 2003

  
YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1601